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# Foreword

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Becoming an effective compliance professional and managing an effective compliance program is extremely challenging. It may be one of the most challenging administrative jobs in health care today. There are many ways to improve your chances of success. Conferences, networking and reading are all effective ways to increase your knowledge and improve your skill set. It is important to stay in touch with your profession. This manual is the most comprehensive written compilation of expert opinion in our profession. It is updated on a regular basis. It has been used by some as an orientation tool and read from front to back. Most use this as a reference tool to resolve complex compliance related issues.

No publication I have worked on, or am aware of, has had more effort put into it. As health care regulatory enforcement continues to ratchet up, resources such as the Health Care Compliance Professional's Manual can be indispensable. Several dozen industry experts, all specialists in their area of expertise, have contributed to this publication. All those who have worked on this have done so with you in mind. We all wish you good fortune in your endeavor to achieve your objective of becoming a more effective compliance professional and maintain an effective compliance program.

*Roy Snell, MHA  
Chief Executive Officer  
HCCA and SCCE  
roy.snell@corporatecompliance.org  
6500 Barrie Rd., Suite 250  
Minneapolis, Minnesota 55435*

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# The Federal Sentencing Guidelines: A Practical Overview of Their Background, Intent, and Implications

## By Gabriel Imperato, Esq. and Anne Novick Branan, Esq.

### ¶30,180 Introduction

In 1991, the U.S. Sentencing Commission capped an intensive, five-year study and drafting effort by promulgating the federal Sentencing Guidelines for Organizational Defendants. The intervening years have proven unequivocally that these guidelines were a watershed in the development of American, perhaps even global corporate law.<sup>\*</sup>

Why? First, the federal Sentencing Guidelines' policies have triggered a substantial shift in the way that government responds to misconduct occurring within organizations. As explained more fully below, the Guidelines tie an organization's exposure to penalties to its efforts to establish a strong compliance program and undertake other "good corporate citizen" actions. Now a growing number of enforcement policies are being modeled on this "carrot and stick" approach, ranging from a civil penalty mitigation policy adopted by the U.S. Environmental Protection Agency to a penalty mitigation policy of the Canadian Competition Bureau. Most important for purposes of this book, the Office of Inspector General (OIG) within the Department of Health and Human Services (HHS) has signaled support for the Guidelines' approach by promoting model Compliance Program Guidances for various health care subindustries. The OIG Compliance Program Guidances stop short of promising reduced penalties for creditworthy compliance programs (as the federal

Sentencing Guidelines do), but they make clear that a demonstrated commitment to compliance can have a liability- and penalty-shielding impact.<sup>1</sup>

A second reason why the federal Sentencing Guidelines represent a kind of watershed is that their definition of "an effective" corporate compliance program has provided the leading framework for an ongoing national dialogue — through conferences, books, newsletters, and best practice forums — on how to build compliance programs that really work. Under the umbrella of the Guidelines' definition, banks, utilities, communications companies, defense contractors, and others have been sharing information on this topic since 1991. In short, the federal Sentencing Guidelines compliance program standards have been the "currency of the realm" in compliance circles over recent years.

The OIG took cognizance of this fact in drafting its Compliance Program Guidances. Its Compliance Program Guidance for Hospitals<sup>2</sup> expressly states that its proposed elements of an exemplary health care compliance program are "based" and "expand upon" the seven elements of the Federal Sentencing Guidelines.<sup>3</sup> This straightforward statement makes it clear, in turn, that the starting point for health care companies in developing a sound and credible compliance program should be understanding the policy behind and the substantial learning that has developed under the federal Sentencing Guidelines for

<sup>\*</sup> This chapter was updated by Gabriel Imperato, Esq. and Anne Novick Branan, Esq. for the September 2016 Health Care Compliance Professional's Manual quarterly report. Gabe Imperato is the Managing Partner of the Fort Lauderdale office of Broad and Cassel and serves on the firm's Executive Committee. He is a member of the Health Law Practice Group and heads up the firm's White Collar Criminal and Civil Fraud Defense Practice Group. Ms. Branan is Of Counsel with the Fort Lauderdale office of Broad and Cassel and has been Board-certified in Health Law by the Florida Bar since 1995. Mr. Imperato and Ms. Branan would like to acknowledge the contributions of Joseph Picone, Esq., an associate at Broad and Cassel.

<sup>1</sup> The guidance for hospitals cites the government's willingness to "consider the existence of an effective compliance pro-

gram . . . when addressing the appropriateness of administrative penalties" as an "example" of the kinds of benefits an organization can receive. OIG, Compliance Program Guidance for Hospitals at 4, n.2, February 1, 1998.

<sup>2</sup> There are over sixteen Compliance Program Guidances and Supplemental Compliance Program Guidances for various aspects of the health care industry, including, among others, hospices, medical equipment companies, nursing homes, and pharmaceutical manufacturers published between 1998 and 2008. See OIG, Compliance Program Guidance, available at, <http://oig.hhs.gov/compliance/compliance-guidance/>.

<sup>3</sup> OIG, Compliance Program Guidance for Hospitals at 7, February 23, 1998.



do to meet the Guidelines' compliance standards. Indeed, because the discussion has been so substantial, it is simply beyond the reach of this chapter to catalog all the learning that has gone on under the Guidelines.

What are presented here, instead, are principles and illustrations that should help the reader understand how to use the Guidelines' compliance definition to build and maintain a creditworthy and effective program (see ¶ 30,220 - ¶ 30,229).

### ¶ 30,220 Understanding the Structure of the Definition

The U.S. Sentencing Guidelines defines a "compliance and ethics program" as "a program designed to prevent and detect criminal conduct."<sup>33</sup> An understanding of the federal Sentencing Guidelines' definition of "an *effective* compliance and ethics program" (emphasis added), however, must begin with an understanding of the structure of that definition. The definition has essentially four parts.<sup>34</sup>

The first part sets forth what might be viewed as overarching requirements. It is, in other words, the "lens" through which the rest of the definition should be viewed and interpreted. According to this first part of the definition, to have an effective compliance and ethics program an organization must exercise due diligence to prevent and detect criminal conduct and otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law. An "effective compliance and ethics program" means a program that has been "reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct." Failure to prevent or detect the instant offense, by itself, does not mean that the program was not effective. The hallmark of an effective program to prevent and detect violations of law is that the organization exercised due diligence in seeking to prevent and detect criminal conduct by its employees and other agents.<sup>35</sup>

(Footnote Continued)

Ethics Officer Association, Health Care Compliance Association, and the Society of Corporate Compliance and Ethics.

<sup>33</sup> United States Sentencing Commission, Guidelines Manual, Ch. 8, § 8B2.1, comment (n. 1.) (2015).

Two principles can be culled from this introductory language. First, "due diligence" is required in the design and follow-through of implementing the program. Second, the object of this diligence is to ensure the program is "generally *effective*" (emphasis added). In short, the Guidelines expect organizations to exert reasonable efforts to ensure that their programs really work. This general, overarching command should be remembered when considering the Guidelines' more specific requirements.

The second part of the definition sets forth seven elements that are required "at a minimum" to satisfy due diligence. Due diligence requires at a minimum that the organization must address the following elements:

1. The organization shall establish standards and procedures to prevent and detect criminal conduct to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct.

2. The organization's governing authority must be knowledgeable about the content and operation of the compliance and ethics program and must exercise reasonable oversight with respect to implementation and effectiveness of the program. High-level personnel of the organization shall ensure that the organization has an effective compliance and ethics program. Specific individual(s) within high-level personnel of the organization must be assigned overall responsibility to oversee compliance with such standards and procedures. Further, specific individual(s) within the organization must be delegated day-to-day operational responsibility for the compliance and ethics program. Individuals with operational responsibility shall report periodically to high-level personnel and, as appropriate, to the governing authority, or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program. These specific individual(s) must be given adequate resources, appropriate authority, and direct access to governing authority.

<sup>34</sup> The definition of an effective compliance and ethics program is set forth at United States Sentencing Commission, Guidelines Manual, Ch. 8, § 8B2.1 (November 2015).

<sup>35</sup> United States Sentencing Commission, Guidelines Manual, Ch. 8, § 8B2.1 (November 2015).



### Who Sets the Standards of Compliance Programs?

3. The organization must use reasonable efforts not to include within the substantial authority personnel of the organization any individual who the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program.

4. The organization must take reasonable steps to communicate effectively its standards and procedures to members of the governing authority, high-level personnel, substantial authority personnel, the organization's employees, and the organization's agents, — by conducting effective training programs and requiring participation in training programs and otherwise disseminating publications that explain in a practical manner what is required.

5. The organization must take reasonable steps to achieve compliance with its standards by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents, periodically evaluating the effectiveness of the compliance and ethics program, and by having in place and publicizing a reporting system that allows for anonymity or confidentiality whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution.

6. The standards must have been consistently promoted and enforced throughout the organization through appropriate incentives for employees to follow the compliance and ethics program and appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense. Adequate discipline of individuals responsible for an offense is a necessary component of enforcement; however, the form of discipline that will be appropriate will be case specific.

7. After a criminal conduct has been detected, the organization must take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct — includ-

ing any necessary modifications to its compliance and ethics program.<sup>36</sup>

It is important to recognize what these “seven elements” are and what they are not. First, the seven elements, while obviously more specific than the introductory paragraph of the definition, are relatively general. For the most part, they describe *types* of required action rather than a highly detailed description of what a program should look like or how to implement the seven steps operationally within an organization. The Office of Inspector General (OIG) Compliance Program Guidances provide further instruction on how to actually craft and operate a compliance program. Prevailing practice among companies has now coalesced around some programmatic features — for example, having a “hotline” of some kind, unless the organization is very small — and these features should be taken as fairly firm guideposts in designing a program that meets the seven elements. But beyond ensuring that they have these kinds of commonly accepted program features, organizations have flexibility in crafting their programs within the broad parameters of the seven elements.

Second, the seven elements are explicitly referred to as the “minimum” requirements of due diligence, signaling that organizations may need to, in a sense, “read into” the Guidelines’ some nonenumerated practices. A compliance program that meets the seven elements has become an expectation of the OIG, as well as the Department of Justice (DOJ), CMS and potential buyers, investors and lenders.<sup>37</sup>

Deciding how to customize the program and knowing which program features to “read into” the federal Sentencing Guidelines’ requirements can be viewed as creating a worrisome degree of uncertainty. After all, if the Guidelines do not explicitly address these issues, how does an organization determine which particular program features to adopt? The answer should be viewed as flowing from both the mandate of the introductory paragraph (adopt

<sup>36</sup> United States Sentencing Commission, Guidelines Manual, Ch. 8, § 8B2.1(b)(1)-(7) (November 2015).

<sup>37</sup> Tony Maida, *New OIG Guidance Signals Changed View of Compliance Programs*, AHLA Weekly, at 5 (May 6, 2016) available

at [https://www.mwe.com/~media/files/experience/health-care-resource-center/recent-notable-government-pronouncements/weekly\\_050616.pdf](https://www.mwe.com/~media/files/experience/health-care-resource-center/recent-notable-government-pronouncements/weekly_050616.pdf).



and implement program features that really work) and also from the third portion of the definition.

The third part of the definition can perhaps be distilled to the following principle: design and implement the program so that it *fits the unique characteristics of the particular organization involved*. The commentary following the definition of an “effective compliance and ethics program” lists factors to consider in meeting the requirements of the Guidelines. The applicable industry practice or standards called for by any applicable government regulation, the organization’s size, and similar misconduct are relevant determinants listed by the Guidelines’ commentary. The Guidelines provide the commentary as follows:

(1) **Applicable governmental regulation and industry practice.** An organization’s failure to incorporate and follow applicable industry practice or the standards called for by any applicable governmental regulation weighs against a finding of an effective compliance and ethics program.

(2) **Size of the organization.** The requisite degree of formality of a program to prevent and detect violations of law will vary with the size of the organization: the larger the organization, the more formal the program typically should be. Meanwhile, a smaller organization must demonstrate the same commitment to ethical conduct and compliance as a large organization but may meet the requirements with less formality and fewer resources than would be expected of large organizations.

(3) **Recurrence of similar misconduct.** Recurrence of similar misconduct creates doubt regarding whether the organization took reasonable steps to meet the requirements of this guideline. Similar misconduct means prior conduct that is similar in nature to the conduct underlying the instant offense without regard to whether or not such conduct violated the same statutory provision.<sup>38</sup> For example, prior Medicare fraud would be misconduct similar to an instant offense involving another type of fraud.

Finally, the fourth part of the Guidelines’ definition provides simply: In implementing the due diligence factors, the organization must periodically

assess the risk of criminal conduct and must take appropriate steps to design, implement, or modify each due diligence factor to reduce the risk of criminal conduct.<sup>39</sup>

This last portion of the commentary stands for the idea that organizations need to periodically assess their compliance and ethics program. If organizations identify risk of criminal conduct in their programs, the organizations need to take steps to reduce these risks.

### ¶ 30,225 2004 Changes to the Sentencing Guidelines

In September 2001, the Ad Hoc Advisory Group on the Organization Sentencing Guidelines (Advisory Group) was commissioned by the United States Sentencing Commission (USSC) with the mandate that it analyze the Organizational Sentencing Guidelines. Note that this was before the enactment of the Sarbanes-Oxley Act (P.L. 107-204) in July 2002. Section 805(a)(2)(5) of the Act directed the USSC to review and amend the Sentencing Guidelines to ensure they were “sufficient to deter and punish organizational criminal misconduct.” The USSC asked the Advisory Group, which was comprised of 15 professionals from many disciplines, to “place particular emphasis on examining the criteria for an effective program to ensure an organization’s compliance with the law.”

The Advisory Group issued a report on October 7, 2003, in which it recommended substantial changes to the Organizational Sentencing Guidelines. The USSC adopted the Advisory Group’s report and formally amended the Organizational Sentencing Guidelines on December 30, 2003. The changes became effective on November 1, 2004.

First, the Advisory Group noted that in spite of compliance programs, it was obvious that substantial corporate wrongdoing by high-level actors at large publicly held organizations went undetected. This caused the Advisory Group to evaluate whether the Organizational Sentencing Guidelines could be made more effective in preventing and detecting legal violations. It concluded that the Organizational Sentencing Guidelines should better

<sup>38</sup> United States Sentencing Commission, Guidelines Manual, Ch. 8, § 8B2.1, comment (n.2) (November 2015).

<sup>39</sup> United States Sentencing Commission, Guidelines Manual, Ch. 8, § 8B2.1(c) (November 2015).



surveys can help quantify how prevalent these issues are.

Sound technique is absolutely critical to the success of any of these measurement approaches. If methodology is poor, the measurement efforts will produce information, but the information may tell a wholly inaccurate story. It is hard to imagine a more dangerous outcome for a compliance program than its design or modification on the basis of false or misleading information.

Measuring the effectiveness of a compliance program is an area that has developed significantly in the last ten years. Many health law attorneys can assist health care providers. Additionally, there are many consultants who have developed methodologies to assess compliance programs. Outsourcing such a function can be an additional expense to a provider, but using outside expertise lends credibility to the process and can actually be more cost effective for the organization.

The effective use of outside consultants may be very helpful, especially at first. Organizations can adopt professional focus group and surveying techniques as their own, but they may need professional guidance to learn these techniques. Such techniques require fewer resources than people think. Because their use can significantly enhance the effectiveness of a compliance program, they can represent a very sound expenditure of resources. Recognizing this bit of learning, the Office of Inspector General has emphasized that health care organizations should use "audits" and "other evaluation techniques" in assessing their compliance programs.<sup>62</sup>

### ¶ 30,245 Back to Health Care: Why the Federal Sentencing Guidelines Are Important

Because health care organizations convicted of health care-related fraud face the dire risk of being excluded from participation in federal benefits programs (e.g., Medicare), some have suggested that the federal Sentencing Guidelines, which only come into

play *after* a conviction, are irrelevant to such organizations. This is a simplistic notion.

What makes the Guidelines critically important to health care organizations is that, as was noted at the outset of this chapter, their framework for effective compliance has become a universal —the "currency of the realm" in compliance circles. HHS has made clear that its model guidances for health care subindustries are based on the federal Sentencing Guidelines,<sup>63</sup> and this is consistent with a more general trend. Thus, it is realistic to believe that, should an organization's compliance program ever be evaluated by any governmental entity, the evaluation will be heavily influenced by the Guidelines' framework.

Just as important, because the field of compliance is young and evolving, health care companies should recognize that the federal Sentencing Guidelines have inspired valuable sharing of compliance "best practice" insights on a regular basis. Because the Guidelines are potentially applicable to all organizations, their compliance framework is openly discussed in public forums, newsletters, and so on by a broad range of organizations that have valuable lessons to share. Health care companies need to participate in this highly informative discussion.

### ¶ 30,250 U.S. Supreme Court Decision Renders Guidelines Advisory

For more than a decade the Guidelines were mandatory and federal judges were required to impose a sentence within the Guidelines unless a specific exception existed. In the event that an exception did exist, the sentencing court would engage in a "departure" from the Guidelines.<sup>64</sup> District Courts were bound by these two options: sentencing within the Guidelines recommended range or departing from the Guidelines based on a specific exemption.<sup>65</sup> In *United States v. Booker*,<sup>66</sup> the Supreme Court held that the right to a trial by jury guaranteed by the Sixth Amendment of the United States Constitution applies to the federal Sentencing Guidelines, and as

<sup>62</sup> OIG, Compliance Program Guidance for Hospitals at 8, February 1, 1998.

<sup>63</sup> See, e.g., OIG Compliance Program Guidance for Hospitals at 7, February 1, 1998.

<sup>64</sup> Melissa Healy, Note: *A Continuing Right to Notice: Why Irizarry v. United States Should Not Be the Last Word for District*

*Courts Imposing Post-Booker Variance Sentences*, 50 Ariz. L. Rev. at 1156 (2008).

<sup>65</sup> Id.

<sup>66</sup> *United States v. Booker*, 543 U.S. 220 (U.S. 2005); (case consolidated with *U.S. v. Fanfan*).



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a result the Sentencing Guidelines were deemed advisory rather than mandatory.

In *Booker*, the trial judge increased the defendant's sentence under the Guidelines by more than eight years based on a finding that the defendant possessed a greater quantity of drugs than was found by the jury. The court in *Booker* had to decide whether the Federal Constitution requires that any penalty beyond the prescribed statutory minimum must be submitted to the jury and proved beyond a reasonable doubt.<sup>67</sup> In determining the Sixth Amendment guarantee of a right to a jury trial applied to the Guidelines, the court affectively shifted the Guidelines from mandatory to advisory.<sup>68</sup> In *Gall v. United States*, the court held that appellate review of sentencing decisions is now limited to determining whether the sentence imposed is "reasonable."<sup>69</sup>

In *Gall*, the court decided that by reviewing the reasonableness of a sentence outside the Guidelines range, appellate courts can take the degree of variance into account and consider the extent of a deviation from the Guidelines.<sup>70</sup> Still, should the sentencing court choose to vary from the Guidelines sentence, it must do so based on the factors in 18 U.S.C. §3553(a), which provides the factors to be considered when imposing a sentence.<sup>71</sup> As a result, judges have significantly more wiggle room to increase or decrease a sentence based on the facts of any individual case, however the judge must offer some reason why he or she did not elect to follow the sentencing guidelines.

Even though the Guidelines are now advisory, the impact on sentencing is negligible, and health care companies should continue to presume that the Guidelines' criteria for an "effective" compliance program remain in force. Any judge sentencing a business entity still is required to examine the adequacy of the entity's compliance program, and if it is

found deficient, can order the company to implement a compliance program that meets the standard defined in the Guidelines. The *Booker/Fanfan* and *Gall* decisions do not have as drastic an effect on businesses and the health care industry as one would expect. Health care companies, as well as all businesses, should continue assessing their compliance programs to make sure they are "effective" for purposes of the federal Sentencing Guidelines because this remains the "gold standard." Courts will continue to consider the Guidelines in an advisory capacity. Businesses with a compliance program that meets the standard in the Guidelines will receive credit in sentencing and fines may be reduced. The seven essential elements of an effective compliance program described earlier should be followed or organizations risk severe consequences regardless of the advisory nature of the Guidelines after the Supreme Court's decisions in *Booker/Fanfan* and *Gall*.

There are six factors a sentencing court must consider in sentencing an organization.:

1. the existence of an "effective compliance and ethics program;"
2. self-reporting, cooperation, or acceptance of responsibility;
3. level of involvement in or tolerance of criminal activity;
4. prior history of the organization;
5. violation of an order; and
6. obstruction of justice.

Factors 1 and 2 weigh in favor of decreasing an organization's sentence. Factors 3 through 6 may increase an organization's punishment. If the organization established and implemented an effective compliance and ethics program before the criminal conduct occurred, factors 3 through 6 may be mitigated.

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<sup>67</sup> Id. at 268

<sup>68</sup> Id. at 245.

<sup>69</sup> *Gall v. United States*, 169 L.Ed. 2d 445 (U.S. 2007).

<sup>70</sup> Id. at 455.

<sup>71</sup> Melissa Healy, *Note: A Continuing Right to Notice: Why Irizarry v. United States Should Not Be the Last Word for District Courts Imposing Post-Booker Variance Sentences*, 50 Ariz. L. Rev. at 1156 (2008).